K 131314

510(k) Summary

1. Submitter:
Swissray Medical AG
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JUN 2 5 2013
Date Prepared: February 6, 2013
Contact: Markus Bütler, Quality Manager

2. Identification of the Device: ddRCruze™ (Digital Mobile Diagnostic X-Ray System);
Recommended classification regulation: 21 CFR 892.1650, 892. 1720
Device class: II, Panel: Radiology, Product code: MQB and IZL

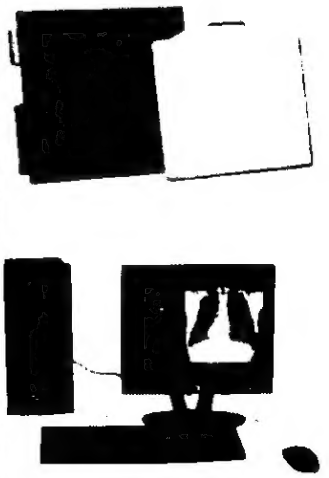
3. Predicate Devices: K101517, Sedecal Mobile Digital Diagnostic X-Ray Systems (various models), manufactured by Sedecal SA (Spain), Software: PrestoDR Portable, K100400, CMT Medical Technologies LTD. The Digital Wi-Fi panel we are using was cleared in our own 510(k): K123005, ddRVersa Motion.

4. A description of the device: This represents the combination of the two of the predicate devices: K101517, Sedecal Mobile Digital Diagnostic X-Ray Systems (various models), manufactured by Sedecal SA (Spain), Software: PrestoDR Portable, K100400, CMT Medical Technologies LTD. (Used UNMODIFIED). ddRCruze™ features a fully motorized mobile DR system, wireless connectivity, diagnostic image quality, viewing monitor for image review and system setup which can be positioned on any side of the system for added convenience. The system has a front-view camera for safe maneuverability.

5. Intended use of the device: Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography) (SAME as predicate)

Comparison Table

Characteristic	Predicate Device K101517, Sedecal Mobile Digital Diagnostic X-Ray Systems (various models),.	PrestoDR Portable, K100400, CMT Medical Technologies LTD.	New Device ddRCruze™
Indications	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography)	The PrestoDR Portable, is intended for use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. PrestoDR 4143 allows imaging of the skull, chest, shoulders, spine, abdomen, and extremities.	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography) (SAME)

Characteristic	Predicate Device K101517, Sedecal Mobile Digital Diagnostic X-Ray Systems (various models),.	PrestoDR Portable, K100400, CMT Medical Technologies LTD.	New Device ddRCruze™
Digital Receptor Panel(s)	Pixium PORTABLE 3543pR: Pixium® CsI coupled to TFT matrix a:Si-technology Pixel size 144 µm Matrix size 2372 x 3000 pixels 16 bit gray scale	Pixium RAD 4600+ and/or Pixium Portable 3543 (WiFi or Cabled) Pixium© CsI on amorphous silicon technology 144 mm 17x14 inch (43.2x34.2 cm) 3,000 x 2,372 pixels 16 bit gray scale	Pixium Portable 3543 EZ Technology Single A-Si TFT + photodiode plate, CsI Scintillator. Active detector area 43 cm x 43 cm, Spatial resolution 3.5 lp/mm Active pixel matrix 2880 x 2880 pixels, Pixel size 148 µm 16 bit gray scale (Cleared in our own 510(k): K123005, ddRVersa Motion.)
Panel Operating Time (battery life)	2 Hours	Up to 8 hours	Up to 8 hours
Panel Communication	Tethered Ethernet or WiFi	Tethered Ethernet or WiFi	Tethered Ethernet or WiFi
Generator	20 kW 32 kW 40 kW 50 kW	Not included	20 kW 32 kW 40 kW 50 kW
Safety	UL Listings and IEC Standards IEC 60601-1 and IEC 60601-1-2, US Performance Standards	UL/CSA Listings and IEC Standards IEC 60601-1 and IEC 60601-1-2, US Performance Standards	UL/CSA Listings and IEC Standards IEC 60601-1 and IEC 60601-1-2, US Performance Standards
Photo			

6. Description of non-clinical tests. The unit has undergone electrical safety and electromagnetic compatibility testing, as well as system integration testing. The technical characteristics of the panel have been measured and included in the bench testing information.

7. Description of clinical tests: Not applicable. Both the mobile system and the digital panel, as well as the software has been previously cleared and is provided unmodified.

8. Conclusions drawn: The nonclinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph 3, above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 25, 2013

Swissray Medical AG
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K131314
Trade/Device Name: ddrCruze™
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB, IZL
Dated: June 10, 2013
Received: June 11, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

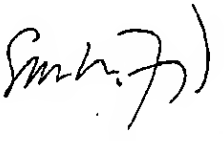
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131314

Device Name: *ddrCruze™*

Indications For Use:

The *ddrCruze™* is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography)

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) _____K131314____